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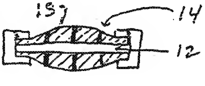
(54) Title: PROSTHETIC COMPONENTS WITH CUSHIONING ELEMENTS



(57) Abstract: A cushioned prosthesis configured for use with a bone having an articular surface including a compressible component (12) and a force-transfer component (13) disposed between the compressive member and the articular surface of the bone.

PROSTHETIC COMPONENTS WITH CUSHIONING ELEMENTS

FIELD OF THE INVENTION

This invention relates generally to prosthetic implants and, more particularly, to devices with cushioning elements, including springs and compressible, resilient members.

BACKGROUND OF THE INVENTION

Artificial disc replacements (ADRs) are frequently made of hydrogels or metal and rubber. Hydrogel ADRs generally surround the hydrogel core with a flexible constraining jacket, as shown in PCT/US00/80920, WO 00/59412.

Unfortunately, the flexibility of the hydrogel and the constraining jacket allow hydrogel ADRs to change shape and extrude through defects in the annulus through which the ADR was inserted, for example. Metal and rubber ADRs often fail at the metal-rubber interface. The rubber fails with the high shear stresses or the rubber separates from the metal with shear stress.

There does exist issued patents that relate to enclosing or sealing hydrogel materials.. Of interest is U.S. Patent No. 6,022,376, which teaches a hydrogel enclosed by a fluid permeable bag. However, the fluid bag does little to protect the hydrogel from shear stress, and the rough texture of the bag may cause hydrogel wear from friction.

U.S. Patent No. 5,002,576 teaches an elastomer enclosed by rigid cover plates and a corrugated tube. The elastomer is sealed from fluids of the body. The corrugated tube allows movement of the cover plates. The corrugated tube may reduce shear forces on the elastomer. U.S. Patent Nos. 5,865,846; 6,001,130; and 6,156,067 teach a spherical articulation between ADR EPs and an elastomer.

The elastomer may be sealed within the ADR EPs. An annular gasket may reduce shear forces on the elastomer. U.S. Patent No 5,893,889 teaches an elastomer that is sealed between ADR EPs. The device uses a ball and socket feature to reduce shear on the elastomer. U.S. Patent No. 6,063,121 incorporates X-shaped wires into the '889 device to reduce rotation.

SUMMARY OF THE INVENTION

This invention relates generally to prosthetic implants and, more particularly, to devices with cushioning elements, including springs and compressible, resilient members.

In most embodiments, the spring(s) compressible member(s) are motion-restricted in some manner, and may be encased, encapsulated, contained, or otherwise protected with one or more rigid components associated with an articulating bone. The embodiments are applicable not only to artificial disc replacement (ADR) devices, but also to joint situations including total knee, hip arthroplasty, elbow, shoulder, wrist and ankle applications.

The compressible materials may include synthetic rubbers, hydrogels, elastomers, and other polymeric materials such as viscoelastic polymers and foam polyurethanes. In such embodiments, the invention effectively combines the advantages of such materials (cushioning, shape memory, and expansion after insertion in the case of hydrogels), while providing increased protection, particularly the elimination of shear stresses. When applied to an ADR, the invention also minimizes the risk of extrusion.

A force-transfer component of some kind is used to couple the compressible member to an articular bone surface, and a container may surround the cushioning element to perform functions such as:

A. Holds the cushion in place.

B. Reduces frictional forces on the cushion element.

C. Reduces shear forces on the cushion element.

D. In some embodiments, seals the cushion element from exposure to the fluids of the body. Body fluids may destroy the cushion element.

E. In some embodiments, retains particle debris.

F. Prevents the ingrowth of tissues that could inhibit motion.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1A is a side view of a contained artificial disc replacement (ADR) of the present invention;

FIGURE 1B shows the cross-section of the device of Figure 1A;

FIGURE 1C is an exploded view of the device of Figures 1A and 1B;

FIGURE 1D is a top view of Figures 1A-1C in position between a pair of adjacent vertebrae;

FIGURE 1E shows the device in a dehydrated state;

FIGURE 1F shows the device in a hydrated/expanded state;

FIGURE 2A shows an ADR according to the present invention disposed symmetrically between adjacent vertebrae;

FIGURE 2B illustrates an asymmetrical configuration;

FIGURE 3A illustrates a device dehydrated for insertion between the vertebrae;

FIGURE 3B illustrates the device expanded after insertion and hydration;

FIGURE 4A shows the device of the present invention with endplates in position;

FIGURE 4B is a cross-section of Figure 4A;

FIGURE 5A is a simplified side view of an alternative embodiment of an ADR;

FIGURE 5B shows a cross-section of the more encapsulated device showing channels for facilitate fluid transfer;

FIGURE 5C is a cross-section showing the hydrogel in a desiccated state;

FIGURE 5D is a cross-section showing the hydrogel in a hydrated, expanded form;

FIGURE 5E shows the side view of the device in place between upper and lower vertebrae;

FIGURE 5F is an anterior-posterior view of the device in place;

FIGURE 6A is a side-view of the device of Figure 5A with inferior and superior end plates attached to the respective vertebrae;

FIGURE 6B is an anterior-posterior view of the device of Figure 6A in position;

FIGURE 7A is an anterior-posterior view of in partial cross-section of an ADR incorporating multiple cylinders;

FIGURE 7B is a side-view, also in partial cross-section;

FIGURE 7C is an axial cross-section of a device containing a central guide cylinder surrounding six pistons;

FIGURE 7D shows two embodiments with multiple cylinders;

FIGURE 8A is a coronal/sagittal cross-section of the cylinders according to the present invention;

FIGURE 8B is an illustration of two vertebrae in extension;

FIGURE 9 shows an embodiment with the peg projecting from the posterior aspect of the inferior surface of the upper plate;

FIGURE 10A shows a further alternative embodiment of the present invention;

FIGURE 10B is a frontal view in cross-section showing partial cushioning;

FIGURE 10C is a frontal cross-sectional view illustrating full cushioning;

FIGURE 11A is a top-down view of an embodiment showing opposing retaining cylinders on either side of a central resilient member;

FIGURE 11B is a side-view drawing in cross-section showing partial cushioning of the device of Figure 11A;

FIGURE 11C is a side-view drawing in partial cross-section illustrating the embodiment of Figures 11A and 11B;

FIGURE 12A shows an anterior-posterior view of the embodiment of the invention wherein the end plates of ADR may contain hollow keels on the vertebral side;

FIGURE 12B is a lateral view of Figure 12A;

FIGURE 12C is a top-down view illustrating the bone ingrowth area of Figure 12A;

FIGURE 13 is a cross-section of an embodiment with multiple pistons connected to the top plate via a rod;

FIGURE 14A is a cross-section illustrating an anterior-posterior view of two pedicle screws;

FIGURE 14B is a cross-sectional lateral view of the embodiment of Figure 14A;

FIGURE 15A is a side-view of a pedicle screw having an axle to receive a shock absorber according to the present invention;

FIGURE 15B is a close-up of the shock absorber mechanism associated with a pedicle screw embodiment of Figure 15A;

FIGURE 16 is a cross-sectional view of a tibial component according to the present invention;

FIGURE 17 is a drawing which shows how a locking component may be incorporated in the design;

FIGURE 18 is a side-view cross-section of a tibial component for a knee replacement;

FIGURE 19 is a side-view drawing of an embodiment illustrating the way in which the invention may be applied to the hip;

FIGURE 20 is a sagittal cross section of the spine and a single cylinder embodiment of the ADR shown in Figure 7;

FIGURE 21A is a sagittal cross section of an alternative embodiment of the ADR;

FIGURE 21B is a sagittal cross section through another embodiment of the ADR shown in Figure 21A;

FIGURE 22 is a sagittal cross section of an alternative embodiment of the ADR shown in Figure 5A;

FIGURE 23A is a sagittal cross section through yet another embodiment of the ADR of the present invention;

FIGURE 23B is a sagittal cross section of the embodiment of the ADR shown in Figure 23A;

FIGURE 23C is a sagittal cross section through an alternative embodiment of the ADR drawn in Figure 23B;

FIGURE 24A is a sagittal cross section through another embodiment of the ADR;

FIGURE 24B is a coronal cross section through the ADR drawn in Figure 24A;

FIGURE 25 is a lateral view of the spine and a multi-component embodiment of the ADR drawn in Figure 2A;

FIGURE 26 is a sagittal cross section through the embodiment of the ADR drawn in Figure 5A;

FIGURE 27 is a view of the top of an alternative embodiment of the ADR drawn in Figure 11A;

FIGURE 28A is a sagittal cross section through an alternative embodiment of the ADR drawn in Figure 13;

FIGURE 28B is a coronal cross section of the embodiment of the ADR drawn in Figure 28A;

FIGURE 29A is a coronal cross section of a constrained embodiment of the ADR shown in Figure 11;

FIGURE 29B is an exploded anterior view of the ADR shown in Figure 29A;

FIGURE 30 is a sagittal cross section of an alternative embodiment of the ADR shown in Figure 11;

FIGURE 31 is a sagittal cross section of an alternative embodiment of the ADR drawn in Figure 22;

FIGURE 32 is a lateral view of an alternative embodiment of the ADR drawn in Figure 21A;

FIGURE 33A is a sagittal cross section of an alternative embodiment of the ADR;

FIGURE 33B is a view of the top of the elastomeric component and the socket of the inferior ADR EP drawn in Figure 33A;

FIGURE 34 is a sagittal cross section of an alternative embodiment of the ADR;

FIGURE 35A is a sagittal cross section of the spine and an alternative embodiment of the device;

FIGURE 35B is a sagittal cross section through another "Disc Spacer" embodiment of the ADR;

FIGURE 36C is a sagittal cross section through another embodiment of the device;

FIGURE 36D is a sagittal cross section through another embodiment of the device;

FIGURE 37A is a lateral view of an alternative embodiment of an ADR according to the present invention;

FIGURE 37B is a sagittal cross section of an embodiment of the ADR similar to that drawn in Figure 21A;

FIGURE 38 is a lateral view of an alternative embodiment of an ADR;

FIGURE 39 is a sagittal cross section through an alternative embodiment wherein the caps and springs are contained in cylinders;

FIGURE 40 is a lateral view of an alternative embodiment wherein the top of the spring caps are concave rather than convex;

FIGURE 41A is a lateral view of an alternative embodiment illustrating the use of a C-shaped spring that cooperates between convex projections from the ADR EPs;

FIGURE 41B is a sagittal cross section through the embodiment of the ADR shown in Figure 41A;

FIGURE 41C is a view of the top of the springs and inferior ADR EP shown in Figure 41A;

FIGURE 41D is a sagittal cross section through an alternative embodiment of the ADR drawn in Figure 41A;

FIGURE 41E is a sagittal cross section through the embodiment of the ADR drawn in Figure 41D;

FIGURE 42 is a lateral view of the spine and an alternative embodiment including spring caps that articulate with a vertebral endplate;

FIGURE 43A is a lateral view of an embodiment of the invention applied to total knee replacement;

FIGURE 43B is sagittal cross section of the embodiment of the device drawn in Figure 43A;

FIGURE 43C is a view of the bottom of upper metal component;

FIGURE 43D is a view of the bottom of an alternative embodiment of the component drawn in Figure 43C incorporating two pistons;

FIGURE 43E is a coronal cross section of the embodiment of the device drawn in Figure 43D;

FIGURE 44A is a sagittal cross section of an alternative embodiment;

FIGURE 44B is a view of the top of the cylinder component of the device drawn in Figure 44A;

FIGURE 45A is a sagittal cross section of an alternative embodiment including a different locking mechanism;

FIGURE 45B is an exploded view of the embodiment of the invention drawn in Figure 45A;

FIGURE 46 is a sagittal cross section through a further embodiment of the invention;

FIGURE 47 is a sagittal cross section through yet a further embodiment of the device;

FIGURE 48 is a sagittal cross section of an alternative embodiment of the invention including hydrogel as a cushion element;

FIGURE 49 is a sagittal cross section of an alternative embodiment of the invention wherein the cushion element is enclosed within a flexible metal component; and

FIGURE 50 is a sagittal cross section of another embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

This invention solves problems associated with artificial disc replacement (ADR) devices and joint-related components, including those associated with total-knee and hip replacements, through the use of compressible/resilient materials, springs, and devices for controlling motion and containing elements in need of protection, for example. In preferred embodiments, the invention effectively combines the advantages of hydrogels and other compressible/resilient materials while minimizing shear stresses. U.S. Patent Nos. 5,047,055 and 5,192,326, both incorporated by reference, list some of the applicable hydrogels. The small size of the desiccated hydrogel facilitates insertion, after which the hydrogel imbibes fluids and expands. Other non-hydrogel compressible and/or resilient materials may alternatively be used, including elastomers, shape-memory polymers, which would increase in height after they are inserted. As another example of many, non-hydrogel polymers such as acrylics may be used which change shape with a change in temperature. Thus, as used herein, the term "hydrogel" should be taken to include other resilient/compressible materials.

The hydrogels are generally protected from shear stress, thereby extending longevity. In particular, the hydrogel is contained, constrained or enclosed within a cavity or cylinder which may include one or more pistons. The hydrogel provides cushioning, while the pistons facilitate articulation either directly or indirectly with bone surfaces. Thus, the invention offers the advantages of metal-on-metal while

providing for cushioning. The hydrogels allow for physiologic tension adjustment since they can change size based upon imbibing fluid and the pressure on the hydrogel. As such, the hydrogel component of the device can change height to balance the forces against the surrounding tissues.

The cylinder and piston would likely be made of metal such as stainless steel, titanium, chrome cobalt, or other biocompatible metal or ceramic alloy. Surfaces to promote bone ingrowth could be used on the covers. The hydrogel embodiments may incorporate channels for the diffusion of fluids in and out of the cylinder. Optional permeable membranes can also be used to prevent extrusion of the hydrogel through the channels. The permeable membrane traps the hydrogel but allows fluids to move freely across the membrane.

Figure 1A is a side view of a contained artificial disc replacement (ADR) according to the invention. Figure 1B is a drawing that shows cross-section of the device of Figure 1A, including a hydrogel-filled chamber 12 and container 13 with channels 14 to permit fluid transfer. Container 13 is preferably rigid but may itself be semi-rigid or constructed of a material such as polyethylene to provide low-friction bearing surfaces. Figure 1C is an exploded view of the device of Figures 1A and 1B showing optional permeable membranes 16, 18. Figure 1D is a top view of Figures 1A-1C in position between a pair of adjacent vertebrae. Figure 1E shows the device in a dehydrated state with the hydrogel 12' assuming a flattened form for easier insertion; Figure 1F shows the device in a hydrated/expanded state.

Devices according to the invention, regardless of disposition in the body, may be placed symmetrically or asymmetrically. Figure 2A shows an ADR according to the invention disposed symmetrically between adjacent vertebrae. Figure 2B illustrates an asymmetrical configuration. Figure 3A illustrates a device dehydrated for insertion between the vertebrae and Figure 3B illustrates the device expanded after insertion and hydration. As shown in Figure 4, endplate covers 20, 21 may be provided in conjunction with the contained hydrogel ADR according to the invention. Figure 4A shows the device and endplates in position. Figure 4B is a cross-section.

Figure 5A is a simplified side view of an alternative ADR according to the invention, wherein the hydrogel 22 is further encapsulated. Figure 5B is a cross-section of the device showing channels 28 for facilitate fluid transfer. Again, a fluid permeable membrane 24 may be useful. Figure 5C is a cross-section of the device

with the hydrogel in a desiccated state. Figure 5D is a cross-section showing the hydrogel in a hydrated, expanded form. Figure 5E shows the device in place between upper and lower vertebrae from a side view. Figure 5F is an A-P of the device in place. Figure 6A is a side-view of the device of Figure 5, with inferior and superior endplates 30, 31 attached to the respective vertebrae. Figure 6B is an A-P view of the device of Figure 6A in position.

The invention may also include two or more cylinders to reduce the tendency of a single assembly to tilt when non-uniform pressure is applied. Figure 7A is an A-P view of in partial cross-section of an ADR held in place with screws such as 32 incorporating multiple cylinders. Figure 7B is a side-view, also in partial cross-section. Figure 7C is an axial cross-section of a device containing a central guide cylinder 34 surrounding six other cylinders such as 36 with a piston being depicted at 36. It will be appreciated that more or fewer guide cylinders and/or pistons may be used as shown, for example, in Figure 10.

Figure 7D shows two embodiments with multiple cylinders. In the partial cushion embodiment (upper drawing), a spherical end 40 of the peg projecting from the top plate rests against and is partially supported by a concavity 42 in the lower plate. In this and other applicable embodiments, any suitable compressible/resilient material may be used, but if the material is hydrogel, holes such as 42 may be provided for fluid transfer. In the full cushion embodiment (lower drawing), the peg projecting from the top plate fits into a restraining cylinder 44. The peg 43 from the top plate does not rest against the bottom plate in this embodiment. In either case, the end of the peg is preferably spherical to allow angular motion between the two plates. The cylinder is shown at 46.

Figure 8A is a coronal/sagittal cross-section of the cylinders according to this embodiment of the invention, showing the hydrogel at 50. The top plate preferably includes a concavity 52 opposite the piston 46. Figure 8B is an illustration of two vertebrae in extension, showing the way in which the front piston 56 is raised and the back piston 58 is lowered. Note that the peg that projects from the lower portion of the upper plate need not be central in location. Figure 9 shows an embodiment with the peg projecting from the posterior aspect of the inferior surface of the upper plate. Posterior peg placement allows a larger anterior cylinder. The larger anterior cylinder

may be better at handling the larger forces placed on the anterior portion of the disc replacement during spinal flexion.

Figure 10A is a top cross-section view of an embodiment showing multiple peripheral cylinders and additional internal hydrogel chambers 66. Among other advantages, this may help to prevent rotatory subluxation of the top component relative to the bottom component while allowing more area centrally for the hydrogels/polymer cylinders. Figure 10B is a frontal view in cross-section showing partial cushioning. Figure 10C is a frontal cross-sectional view illustrating full cushioning.

Two or more retaining cylinders may also be used to reduce the shear on the compressible/resilient material, be it a solid piece of silicone rubber, elastomer or hydrogel-type material. Figure 11A is a top-down view of an embodiment showing opposing retaining cylinders 68 on either side of a central resilient member 70. Figure 11B is a side-view drawing in cross-section showing partial cushioning of the member 70. Figure 11C is a side-view drawing in partial cross-section illustrating the embodiment of Figures 11A and 11B providing a full cushioning and reduced shear capability.

Reference is now made to Figure 12A, which is an A-P view of the embodiment of the invention wherein the end plates of ADR may contain hollow keels on the vertebral side. Figure 12B is a lateral view and, Figure 12C is a top-down view illustrating the bone ingrowth area 72. The vertebrae would be osteotomized to make room for the keels. The bone from the osteomity sites would be morselized and placed inside the hollow keels. The morselized bone would promote ingrowth into the end plates of the ADR, much like hollow cages promote bone ingrowth.

Figure 13 is a cross-section of an embodiment with multiple pistons 74 connected to the top plate 76 via rods 78, much like the design of rods that connect pistons to a crankshaft in an engine. The shock absorber concept according to this invention may also be used with respect to vertebral shock absorbers. The compressible/resilient material, again preferably a hydrogel, is depicted at 80. Figure 14A is a cross-section illustrating an A-P view of two pedicle screws 81, 83 coupled in this way. The piston is shown at 82 and the compressible/resilient material is depicted at 84. Figure 14B is a cross-sectional lateral view of the embodiment of

Figure 14A. The piston is shown at 82 and the compressible/resilient material is depicted at 84.

Figure 15A is a side-view of a pedicle screw having an axle 86 to receive a shock absorber according to the invention. A holding nut is shown at 88. Figure 15B is a close-up of the shock absorber mechanism associated with a pedicle screw embodiment. The piston is shown at 90 and the compressible/resilient material is depicted at 92. An attachment is shown at 94, and a hole for coupling to a pedicle screw is shown at 96.

The cylinders could be made of ceramic, metal, or metal lined with ceramic. The pistons could also be made of metal, ceramic, alloys and so forth. In any case, the articulation of the top and bottom plates is preferably metal-to-metal or ceramic-to-metal, both of which are presumably superior to metal-to-polyethylene articulations. As discussed elsewhere herein, hydrogels, shape-memory polymers, or other polymers within the cylinder provide a cushion, or dampen the forces across the plates. Polymers of different durometers could be used in cylinders in different locations. For example, the polymers in the posterior cylinders could be less compressible and therefore help resist extension of the spine. The cylinders could also use liquids with baffles to dampen motion. That said, hydrogels or polymers have the benefit of functioning without a water tight cylinder piston unit. Indeed, as mentioned previously, the cylinders or the pistons may contain holes to allow fluid movement in the hydrogel configurations.

As discussed above, this invention is not limited to the spine, but may be used in other joint situations such as the knee and hip, which typically use polyethylene bearing surfaces on the acetabulum or proximal tibia. Problems related to polyethylene wear are well known to orthopedic surgeons. Although metal-on-metal and ceramic-on-ceramic total hips have been developed to reduce the problems associated with poly wear, such designs do not provide shock-absorbing capacity. For example, excessive force form tight ligaments about the knee or hip may reduce the size of the hydrogel, thus reducing the tension on the ligaments. Conversely, loose ligaments will cause the hydrogel to swell, thus increasing the tension on the loose ligaments. Although hydrogels are used in this preferred embodiment as well, other elastomers and polymers including shape memory polymers may alternatively be used.

Figure 16 is a cross-sectional view of a tibial component according to the invention. The compressible/resilient material is depicted at 98. Channels 99 may be provided for fluid transfer, and these may be located around the periphery, or near the center, rather than in the weight-bearing area. Figure 17 is a drawing which shows how a locking component 100 may be incorporated in the design which allows movement while, at the same time, prevent disassociation. A similar design may be used for other prosthetic components, including a patella button.

Figure 18 is a side-view cross-section of a tibial component for a knee replacement utilizing a central guide 102 and peripheral pistons 104, 106, much like the vertebral embodiments discussed with reference to Figures 7-11, in particular.

Figure 19 is a side-view drawing of an embodiment illustrating the way in which the invention may be applied to the hip. As shown in the drawing, an inner cup 108 would be used with respect to the acetabulum, along with an outer bearing surface with a compressible/resilient material such as a hydrogel/elastomeric or other polymeric material 110 being used therebetween. Particularly with regard to a hydrogel configuration, one or more channels 112 for fluid transfer may be provided.

Figure 20 is a sagittal cross section of the spine and a single cylinder embodiment of the ADR drawn in Figure 7. Keels 114, 116 from the ADR EPs project into the vertebrae above and below the ADR.

Figure 21A is a sagittal cross section of an alternative embodiment of the ADR. The cushion element 120 is located into a somewhat flexible shell 122. The shell 122 in this case completely isolates the cushion element from exposure to the fluids of the body. The walls of the shell reversibly bend in response to axial loads. The shell could be made of plastic, polyethylene, or a flexible metal such as titanium. The upper ADR EP articulates with the shell. The shell may either articulate with lower ADR EP or the shell may snap into the lower ADR EP. The shell could be filled with a liquid form of the cushion material. The cushion material could polymerize, or cure, within the shell. The thickness of the walls of the shell could vary. For example, the top and bottom of the shell could be thicker than the sides of the shell. The thin side walls would encourage bending through the side walls rather than the top and bottom of the shell. Figure 21B is a sagittal cross section through another embodiment of the ADR drawn in Figure 21A. The cushion material is

contained within a hollow area in the inferior ADR EP. The upper and lower ADR EPs articulate.

Figure 22 is a sagittal cross section of an alternative embodiment of the ADR drawn in Figure 5A. The bottom component of the ADR drawn in Figure 5A has a keel to attach the ADR to the vertebra inferior to the ADR. The upper component of the ADR drawn in Figure 5A articulates with an ADR EP. The gap between the walls of the ADR and the cushion element allow the cushion element to expand radially with axial compression. Elastomers that contain air, such as "foam polyurethane" require less space for expansion with axial loads. The air within the elastomer is compressible.

Figure 23A is a sagittal cross section through another embodiment of an ADR according to the invention, wherein the cushion element 124 is contained between ADR EPs. A flexible band 126 attaches to the upper and lower ADR EPs to prevent exposure of the cushion element to the fluids of the body. The cushion element may not be attached to either ADR EP. Fluid, such as an oil, gel or other suitable fluid, could be contained within the ADR. Alternatively, the outer, flexible band could be fluid permeable to permit fluid transfer in hydrogel containing embodiments.

Figure 23B is a sagittal cross section of the embodiment of the ADR drawn in Figure 23A, showing how a portion of the outer band 126 can be detached from one of the ADR EPs to create a window into the ADR, allowing the cushion element 124 to be replaced through the window. The cushion element could be sealed by a "fluid tight" membrane. The fluid tight membrane could also contain a fluid. The outer band could be reattached to the upper ADR EP after changing the cushion element. Hydrogel containing embodiments would not require a detachable outer band. The hydrogel containing embodiment could be placed into the disc space with a partially dehydrated hydrogel. The outer band would no longer be required to provide a fluid impermeable barrier. Further, in Figure 23A, the outer, flexible band could be fluid permeable to permit fluid transfer in hydrogel containing embodiments. Note also that in Figure 23B, the hydrogel containing embodiments would not require a detachable outer band since the device could be placed into the disc space with a partially dehydrated hydrogel.

Figure 23C is a sagittal cross section through an alternative embodiment of the ADR drawn in Figure 23B, wherein the cushion element is capped with a material

that reduces friction between the ADR EPs and the cushion component. For example, polyethylene or chrome cobalt caps could press fit into the top and bottom of the cushion element.

Figure 24A is a sagittal cross section through another embodiment of the invention, including a novel keel that limits shear stress on the cushion element. Such a keel preferably allows at least 10 degrees of flexion, 5 degrees of extension, and 2.5 degrees of lateral bending in each direction, and 2 degrees of axial rotation in each direction. A donut shaped cushion element 130 surrounds the keel. Figure 24B is a coronal cross section through the ADR drawn in Figure 24A. The keel 132 of the upper ADR EP cooperates with a slot 134 within the lower ADR EP to allow the motions mentioned above.

Figure 25 is a lateral view of the spine and a multi-component embodiment of the invention, wherein multiple cushion components are connected together. For example, the components can be connected to a band that surrounds the components. The cushion components could rotate about axles connected to the band. Figure 26 is a sagittal cross section of an embodiment of the invention, wherein upper and lower components 136, 138 are connected by a flexible tension band 140. The band prevents dissociation of the components.

Figure 27 is a view of the top of an alternative embodiment of the ADR drawn in Figure 11A, wherein the cylinders 140, 142 that cooperate with the pistons are elongated to allow translation. Alternatively, the cylinders could have a central torodial region to allow translation.

Figure 28A is a sagittal cross section through an alternative embodiment of the ADR drawn in Figure 13, including at least one piston connected to the upper ADR EP by an axle or axles such as 146. Figure 28B is a coronal cross section of the embodiment of the ADR drawn in Figure 21A. Such hinged pistons facilitate ADR flexion and extension. A loose fit between the piston and the cylinder would also permit a few degrees of lateral bending. A single piston embodiment allows unlimited axial rotation. The piston or pistons can be located centrally or in non-central locations. For example, the piston could be located in the posterior half of the ADR.

Figure 29A is a coronal cross section of a constrained embodiment of the invention, wherein the balls on the pistons will not fit through the openings in the

cylinders of the ADR. Figure 29B is an exploded anterior view of the ADR drawn in Figure 22A. The balls 148, 149 for the pistons are threaded onto the pistons through openings 150, 152 on the bottom of the inferior ADR EP. Screws 154, 156 can be used to close the openings in the inferior ADR EP.

Figure 30 is a sagittal cross section of an alternative embodiment of the invention, wherein the shaft 158 of the piston is located eccentrically on the ball at the end of the piston. The shaft of the piston selectively impinges with the walls of the cylinder to limit ADR motion. For example, the impingement could limit ADR extension.

Figure 31 is a sagittal cross section of an alternative embodiment of the invention, wherein the shaft of the piston selectively impinges on a projection from the walls of the cylinder to limit ADR motion. For example, the impingement could limit ADR extension.

Figure 32 is a lateral view of an alternative embodiment of the invention, wherein a slot allows the axle to translate forward and backward, facilitating translation of the ADR EPs.

Figure 33A is a sagittal cross section of an alternative embodiment of the invention, wherein a ball-and-socket joint 159 is located in the posterior aspect of the ADR. A cushion element 160 is located anterior to the ball and socket joint 159. The cushion element could be made of polymers or springs. Figure 33B is a view of the top of the elastomeric component and the socket of the inferior ADR EP drawn in Figure 33A.

Figure 34 is a sagittal cross section of an alternative embodiment of the invention, including a projection from the piston or pistons fit through a slot in the top of the cylinder/cylinders. The two ADR EPs can be rotated after inserting the projection through the slot thus, reversibly locking the ADR EPs together. The projection could also interact with the top of the cylinder to limit ADR motion.

Figure 35A is a sagittal cross section of the spine and an alternative embodiment of the invention, including a piston and cylinder containing members articulate with the vertebral endplates, they are not fastened to the endplates of the vertebrae. All of the embodiments drawn in this application could be converted into similar "disc spacer" ADRs. Articulation between the components can be located centrally or eccentrically. For example, the articulation may be located in the

posterior half of either component or both components. The drawing illustrates a posterior location of the articulation.

Figure 35B is a sagittal cross section through another "disc spacer" embodiment of the invention, wherein the end of the piston contains a spherical enlargement. For example, the ball and socket of Figure 9A shown in my co-pending U.S. Patent Application entitled "Artificial Intervertebral Disc Spacers," incorporated here by reference in its entirety, can be surrounded by a viscoelastic or other compressible/resilient component. Figure 35C is a sagittal cross section through another embodiment of the invention, wherein the disc spacer articulates with ADR EPs as described the co-pending application discussed above. Figure 35D is a sagittal cross section through another embodiment of the invention, wherein the piston component projects from the inferior ADR EP. The cylinder component articulates with the piston component and a superior ADR EP. This two-articulation embodiment is similar to a "cushioned" embodiment of the two articulation ADRs is also described in the co-pending U.S. patent application referenced above.

Figure 36A is a lateral view of a variation including a superior ADR EP that articulates with convex caps which, in turn, articulate with, or are connected to, springs. The articulation between the ADR EP and the caps reduces shear on the springs and on the connection of the springs to the surrounding components. Figure 36B is a view of the top of the convex caps and the bottom ADR EP of the embodiment of the ADR drawn in Figure 36A. Any number of springs and caps can be used in the novel ADR. For example, the ADR could use one to twenty springs or more.

Figure 36C is a sagittal cross section through an embodiment of the ADR similar to that drawn in Figure 36A. The inferior ADR EP in Figure 36C has posts that hold the springs in position. Figure 36D is a sagittal cross section through the ADR drawn in Figure 36C. The upper ADR EP is tilted with respect to the lower ADR EP as would be seen with spinal movement. The spring on the left is compressed. The post from the inferior ADR EP is articulating with the spring cap. Articulation between the spring cap and the post, limit the amount of compression applied to the spring. Movement occurs through the articulation between the spring cap and the upper ADR EP, and between the spring cap and the post from the lower ADR EP.

Figure 37A is a lateral view of an alternative embodiment of an ADR according to the invention, wherein the springs articulate directly with the ADR EPs. The superior ADR EP has convex surfaces that articulate with the springs. The lower ADR EP could have similar convex surfaces. Alternatively, the springs could be connected to or articulate with a flat surface on the lower ADR EP.

Figure 37B is a sagittal cross section of an embodiment of the ADR similar to that drawn in Figure 37A. The springs surround posts from the inferior ADR EP.. The surface on the top of the post is concave to articulate with the convex projections from the upper ADR EP. The ADR also has an optional component to seal the springs and the articulating surfaces from the body. The seal traps debris from the articulating surfaces. The seal can also be used to contain a lubricating fluid. Various oils or other suitable fluids or gels could be used inside the ADR.

Figure 38 is a lateral view of an alternative embodiment of an ADR, wherein multiple springs cooperate with a single cap. Figure 39 is a sagittal cross section through an alternative embodiment wherein the caps and springs are contained in cylinders. Figure 40 is a lateral view of an alternative embodiment wherein the top of the spring caps are concave rather than convex as drawn in Figure 20A.

Springs of other types can be used in this and the other embodiments of this invention. For example, Figure 41A is a lateral view of an alternative embodiment illustrating the use of a C-shaped spring that cooperates between convex projections from the ADR EPs. Figure 41B is a sagittal cross section through the embodiment of the ADR drawn in Figure 41A. Figure 41C is a view of the top of the springs and inferior ADR EP drawn in Figure 41A. Figure 41D is a sagittal cross section through an alternative embodiment of the ADR drawn in Figure 41A. The C-shaped springs are preferably circular in cross section. Figure 41E is a sagittal cross section through the embodiment of the ADR drawn in Figure 41D. The inferior ADR EP has posts to hold the springs in position.. The springs articulate with the flat surface of the inferior ADR EP.

Figure 42 is a lateral view of the spine and an alternative embodiment including spring caps that articulate with a vertebral endplate. The use of independent springs allow the ADR to better conform to the vertebral endplate. For example, one or more of the springs can extend more completely to fill concavities within the vertebral endplates.

Figure 43A is a lateral view of an embodiment of the invention applied to total knee replacement. A cushion element 202 is located between two metal components 204, 206. The tibial component preferably further includes a polyethylene piece 210. Figure 43B is sagittal cross section of the embodiment of the device drawn in Figure 43A. At least one piston configuration is used to limit shear force on the cushion element. Figure 43C is a view of the bottom of upper metal component. A single piston 220 can be seen on the bottom of the component.

Figure 43D is a view of the bottom of an alternative embodiment of the component drawn in Figure 20C incorporating two pistons 240, 250. Two or more pistons can be used to eliminate rotation between the two metal, or ceramic, components. Eliminating rotation also reduces the shear stresses on the cushion component. Figure 43E is a coronal cross section of the embodiment of the device drawn in Figure 43D.

Figure 44A is a sagittal cross section of an alternative embodiment including an arrangement to lock the components together. A projection 260 from the side of the piston fits into a slot shaped opening 262 in the top of the cylinder. Rotating the two components traps the projection from the piston in the cylinder. Figure 44B is a view of the top of the cylinder component of the device drawn in Figure 44A, illustrating the oblong cylinder opening.

Figure 45A is a sagittal cross section of an alternative embodiment including a different locking mechanism. The assembled components are locked together. Figure 45B is an exploded view of the embodiment of the invention drawn in Figure 45A. The cushion element is illustrated at 270. A preferably circular component 272 is threaded onto the piston, after the piston is placed through cushion component and into the cylinder. A screw 274 is used to close the bottom of the cylinder.

Figure 46 is a sagittal cross section through another embodiment of the invention, wherein a tibia component pistons in the lower component. A seal 280 can be seen between the two components (dark circles). The upper component also has one or more pistons that move within cylinders in the lower component. The upper and lower components can be non-circular in shape to prevent rotation.

Figure 47 is a sagittal cross section through another embodiment of the device. The cushion element (area of the drawing with diagonal lines) is contained within

cylinders in the tibial and femoral canals. A membrane is used to seal the tibial component. Seals are also illustrated on the femoral components (dark circles).

Figure 48 is a sagittal cross section of an alternative embodiment of the invention including hydrogel as a cushion element 302. A flexible, preferably fluid permeable membrane 304 surrounds the hydrogel. Axial loads on the hydrogel are converted into hoop stress on the flexible membrane. In the preferred embodiment the flexible membrane is elastic. The flexible membrane or components above and below the hydrogel may contain pores for fluid transfer. This embodiment of the device is also described in co-pending U.S. patent application Serial No. 10/407,554, entitled "Artificial Intervertebral Disc Replacements Incorporating Reinforced Wall Sections."

Figure 49 is a sagittal cross section of an alternative embodiment of the invention wherein the cushion element is enclosed within a flexible metal component. The cushion component, a sealed elastomer, or hydrogel, for example, is not exposed to the fluids of the body, which can degrade some materials. A somewhat similar device is described in co-pending provisional patent application Serial No. 60/445,489, entitled "Improved Longevity Elastic Components For ADRs."

Figure 50 is a sagittal cross section of another embodiment of the invention, wherein an elastic component surrounds pieces that move along inclined planes. Loads on the upper tibial component force the moveable outward. The cushion component forces the movable components together as the load is removed from the tibial component. The elastic component is not exposed to shear or compression. The elastic component is only exposed to tension. This embodiment of the device is also described in co-pending provisional patent application Serial No. 60/445,958, entitled "Composite Components For Disc And Joint Replacements."

I claim:

1. A cushioned prosthesis configured for use with a bone having an articular surface, comprising:

a compressible component; and

a force-transfer component disposed between the compressible member and the articular surface of the bone.

2. The cushioned prosthesis according to claim 1, wherein the compressible component is a hydrogel.

3. The cushioned prosthesis according to claim 2, further including one or more channels through the housing or piston to permit fluid transfer.

4. The cushioned prosthesis according to claim 1, wherein the compressible member is a synthetic rubber, hydrogel, elastomer, viscoelastic polymer, shape-memory polymer, or foam polyurethane.

5. The cushioned prosthesis according to claim 1, wherein the force-transfer component has a surface physically configured to interact with a vertebral endplate.

6. The cushioned prosthesis according to claim 1, wherein the force-transfer component has a surface physically configured to interact with one or more natural or artificial femoral condyles.

7. The cushioned prosthesis according to claim 1, wherein the force-transfer component has a surface physically configured to interact with a natural or artificial proximal tibia.

8. The cushioned prosthesis according to claim 1, wherein the force-transfer component has a surface physically configured to interact with a natural or artificial femoral head.

9. The cushioned prosthesis according to claim 1, wherein:

the compressible component is sealed within a housing; and

the force-transfer component form on of the walls of the housing.

10. The cushioned prosthesis according to claim 1, further including a device to limit the movement of the force-transfer component.

11. The cushioned prosthesis according to claim 10, wherein the device includes a piston and cylinder arrangement.

12. The cushioned prosthesis according to claim 11, wherein the piston terminates in a ball-shaped end.

13. The cushioned prosthesis according to claim 11, wherein the piston and cylinder arrangement has an asymmetric cross section.

14. The cushioned prosthesis according to claim 1, wherein the force-transfer component is contained within a housing with sidewalls to limit shear stress.

15. The cushioned prosthesis according to claim 1, wherein compressible component in combination with the force-transfer component form an intervertebral disc spacer.

16. The cushioned prosthesis according to claim 15, further including a pair of opposing endplates between which the disc spacer is positioned.

17. The cushioned prosthesis according to claim 1, wherein the compressible component is a spring or springs.

18. The cushioned prosthesis according to claim 17, further including a pair of opposing plates; and

the spring or springs are disposed between plates to urge them apart.

19. The cushioned prosthesis according to claim 18, further including a concave or convex surface on one of the plates where one of the springs contacts that plate.

20. The cushioned prosthesis according to claim 19, further including one or more features that impinge or otherwise limit the load on the spring or springs.

21. The cushioned prosthesis according to claim 20, including a spring disposed in a cylinder.

22. The cushioned prosthesis according to claim 20, including a spring disposed over a post.

23. The cushioned prosthesis according to claim 19, wherein the point where the spring contacts the concave or convex surface results in a joint having a center of rotation.

24. The cushioned prosthesis according to claim 23, wherein the joint is spherical.

25. The cushioned prosthesis according to claim 23, including a plurality of springs, each forming a joint having a center of rotation.

26. The cushioned prosthesis according to claim 25, wherein the centers of rotation cooperate to form an overall center of rotation for the ADR.

27. The cushioned prosthesis according to claim 1, further including a mechanism that allows the force-transfer component to telescope while limiting a full pull-out.

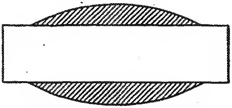


Fig - 1A

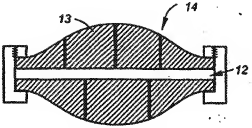


Fig - 1B

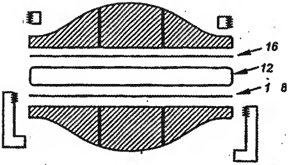


Fig - 1C

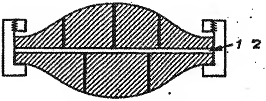


Fig - 1E

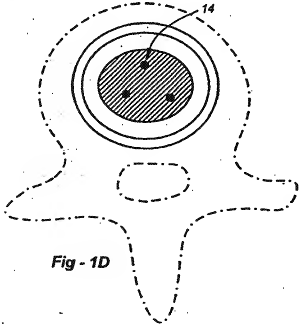


Fig - 1D

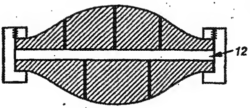
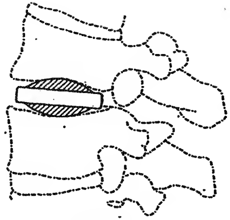


Fig - 1F



F g - 2A

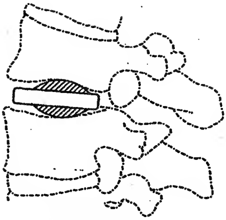
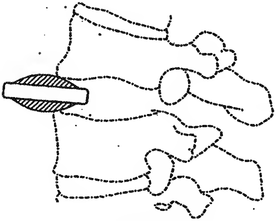


Fig - 2B



F'g - 3A

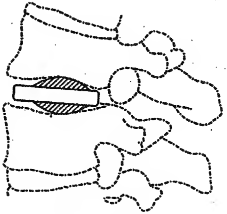


Fig - 3B

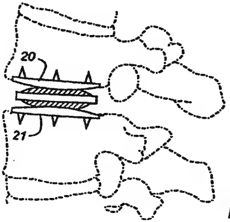


Fig - 4A

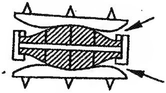


Fig - 4B

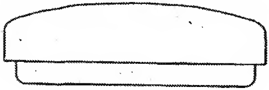


Fig - 5A

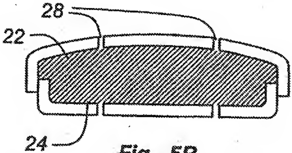


Fig - 5B

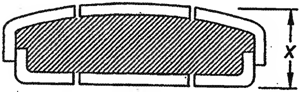


Fig - 5 C

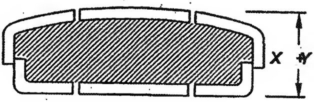


Fig - 5D

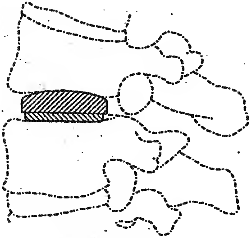


Fig - 5E

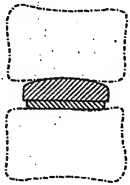


Fig - 5F

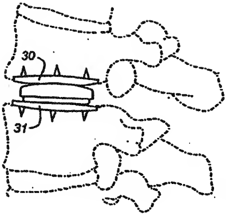
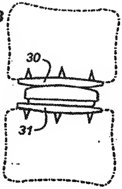


Fig - 6A

Fig - 6B



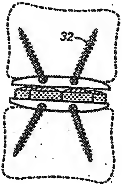


Fig - 7A

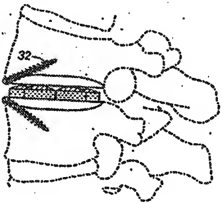


Fig - 7B

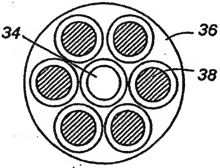


Fig - 7C

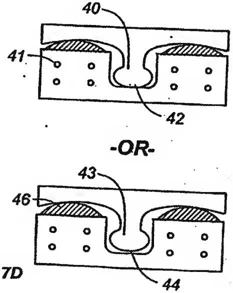


Fig - 7D

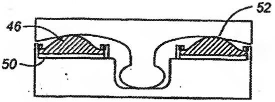


Fig - 8A

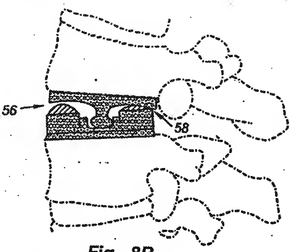


Fig - 8B

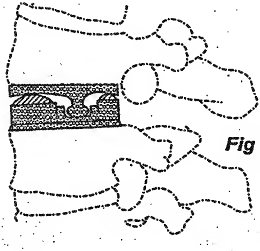


Fig - 9

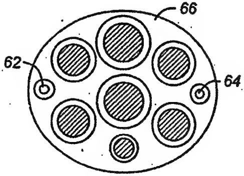


Fig - 10A

Fig - 10B

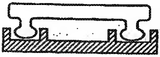


Fig - 10C

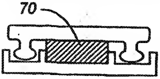


Fig - 11B

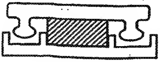


Fig - 11C

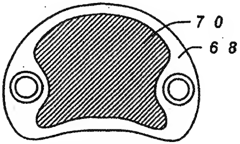


Fig - 11A

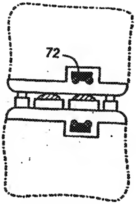


Fig - 12A

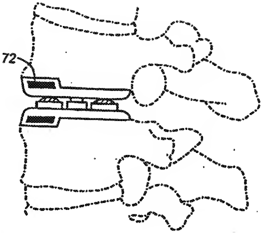


Fig - 12B

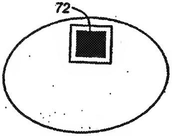


Fig - 12C

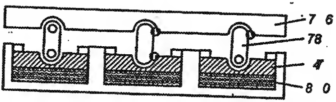


Fig - 13

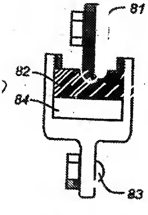


Fig - 14A

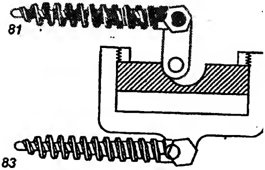


Fig - 14B

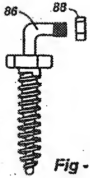


Fig - 15A

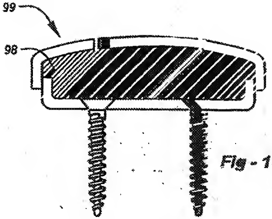


Fig - 16

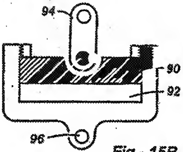


Fig - 15B

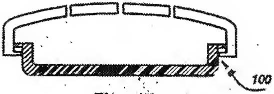
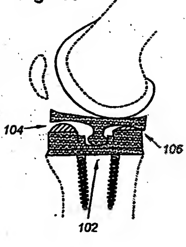


Fig - 17

Fig - 18



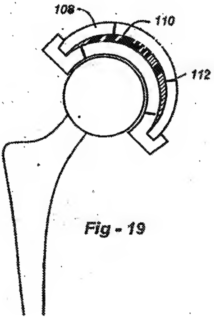
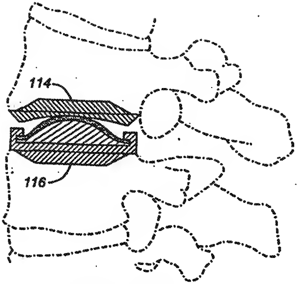


Fig - 19



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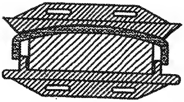


Fig - 22

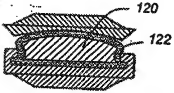
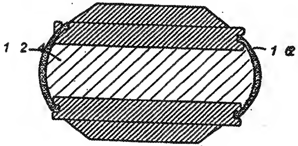
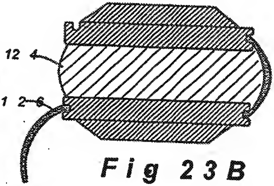


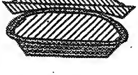
Fig - 21A



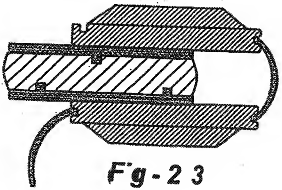
Fg - 2 3 A



F i g 2 3 B



Fg - 12B



Fg - 2 3

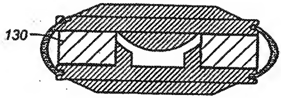


Fig - 24A

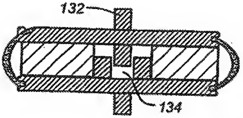
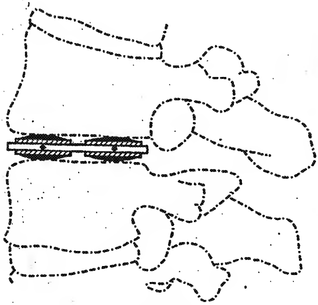


Fig - 24B



F'g - 2 5

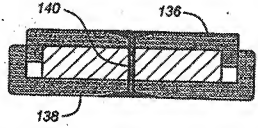


Fig - 26

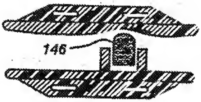
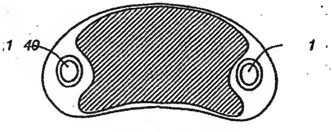


Fig - 28A



F'g -2 7

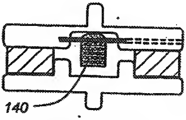


Fig - 28B

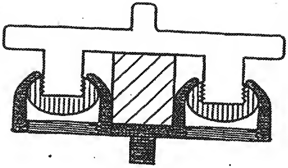


Fig - 29A

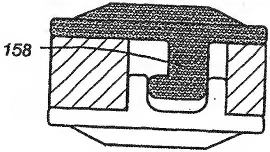


Fig - 30

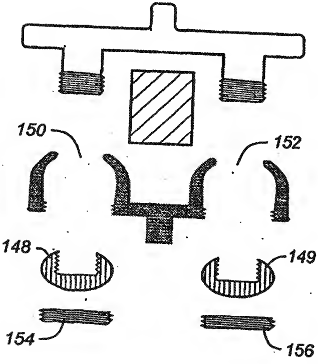


Fig - 29B

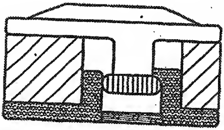


Fig - 31

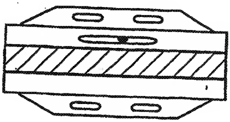


Fig - 32

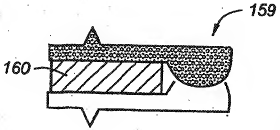


Fig - 33A

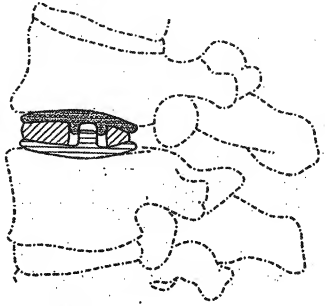


Fig - 35A

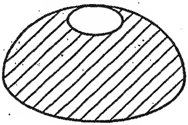


Fig - 33B

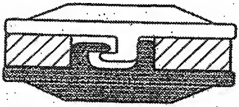


Fig - 34

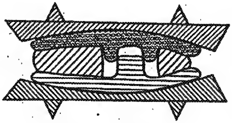


Fig - 35C

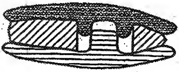


Fig - 35B

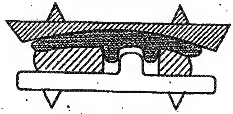


Fig - 35D

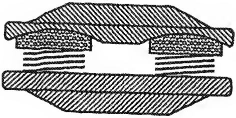


Fig - 36A

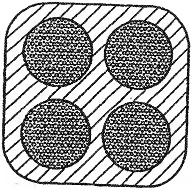


Fig - 36B

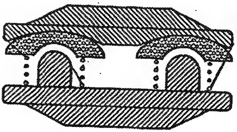
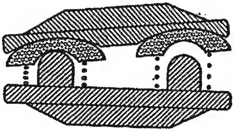


Fig - 36C



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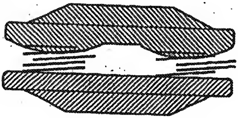

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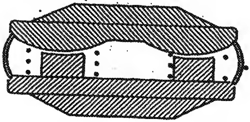
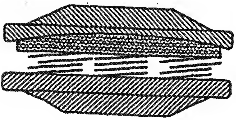


Fig - 37B



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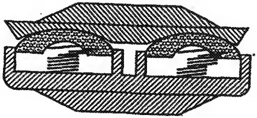

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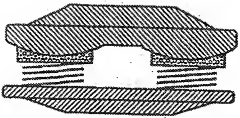


Fig - 40

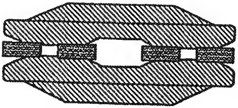


Fig - 41A

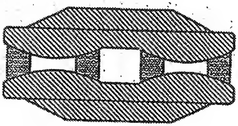


Fig - 41B

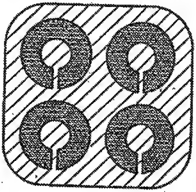


Fig - 41C

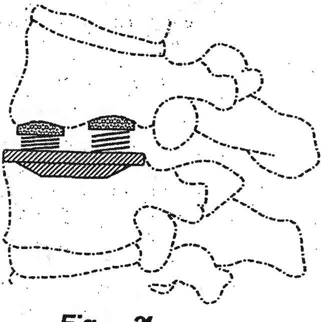


Fig - 24

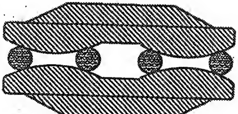


Fig - 41D

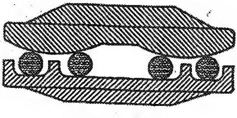


Fig - 41E

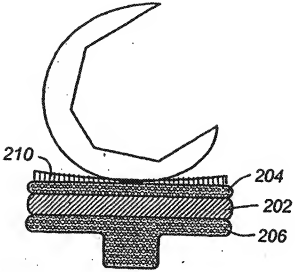


Fig - 43A

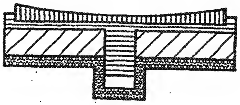


Fig - 43B

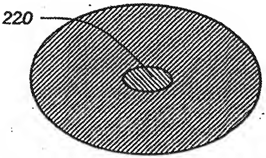


Fig - 43C

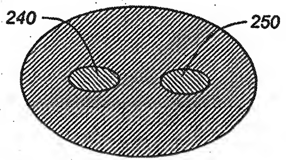


Fig - 43D

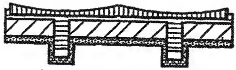


Fig - 43E

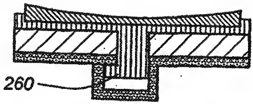


Fig - 44A

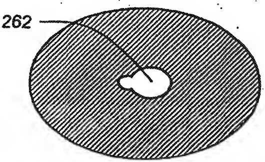
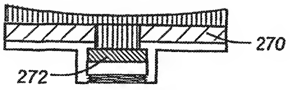


Fig - 44B



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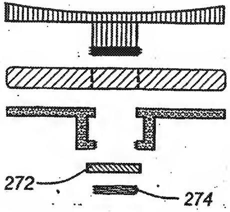

Fig - 45B

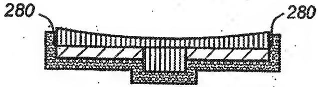

Fig - 46

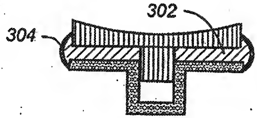

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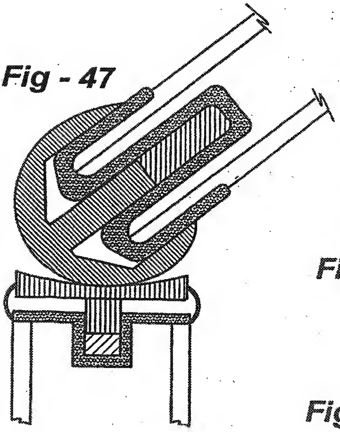
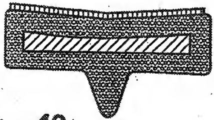
Fig - 47





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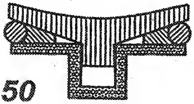

Fig - 50

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/14764

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/44
US CL : 623/17.15

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/17.15, 17.11, 17.12, 17.13, 20.11, 20.28, 22.13, 22.14, 23.17

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
none

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
none

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00/64385 A (LI et al) 02 November 2000, see entire document including page 15, lines 16-20 teaching external surfaces, walls, barriers, supports, etc.	1-10, 14-16
X	US 4,309,777 A (PATIL) 12 January 1982, see entire document.	1, 5, 9-11, 14-18
X, P	US 6,508,841 B2 (MARTIN et al) 21 January 2003, see all embodiments and column 4, lines 3-15, teaching "compression or elongation".	1, 6-11, 14, 17, 27
X	US 5,389,107 A (NASSAR et al) 14 February 1995, see all embodiments.	1, 8-11, 14, 17, 27
X, P	US 6,527,806 B2 (RALPH et al) 04 March 2003, see entire document.	1, 5, 10, 14-21, 23, 25-27

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
08 July 2003 (08.07.2003)

Date of mailing of the international search report
15 AUG 2003

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